IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES *ex rel.* STEFAN KRUSZEWSKI, STATE OF ILLINOIS *ex rel.* STEFAN KRUSZEWSKI; STATE OF ARKANSAS *ex rel.* STEFAN KRUSZEWSKI; STATE OF CALIFORNIA *ex rel.* STEFAN KRUSZEWSKI; STATE OF DELAWARE *ex rel.* STEFAN KRUSZEWSKI; STATE OF FLORIDA *ex rel.* STEFAN KRUSZEWSKI; STATE OF HAWAII *ex rel.* STEFAN KRUSZEWSKI; STATE OF INDIANA *ex rel.* STEFAN KRUSZEWSKI; STATE OF LOUISIANA *ex rel.* STEFAN KRUSZEWSKI; STATE OF MASSACHUSETTS *ex rel.* STEFAN KRUSZEWSKI; STATE OF MONTANA *ex rel.* STEFAN KRUSZEWSKI; STATE OF MICHIGAN *ex rel.* STEFAN KRUSZEWSKI; STATE OF NEVADA *ex rel.* STEFAN KRUSZEWSKI; STATE OF NEW HAMPSHIRE *ex rel.* STEFAN KRUSZEWSKI; STATE OF NEW MEXICO *ex rel.* STEFAN KRUSZEWSKI; STATE OF TENNESSEE *ex rel.* STEFAN KRUSZEWSKI; STATE OF TEXAS *ex rel.* STEFAN KRUSZEWSKI; COMMONWEALTH OF VIRGINIA *ex rel.* STEFAN KRUSZEWSKI; and DISTRICT OF COLUMBIA *ex rel.* STEFAN KRUSZEWSKI

Plaintiffs,

v.

ASTRAZENECA

06 -4004

CIVIL ACTION NO.

FILED IN CAMERA

AND UNDER SEAL

JURY TRIAL DEMANDED

PHARMACEUTICALS, LP :
:
Defendant. :

COMPLAINT

The United States of America *ex rel.* Stefan Kruszewski; the States of Illinois, California, Delaware, Florida, Hawaii, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Mexico, Tennessee, Texas, Virginia and the District of Columbia *ex rel.* Stefan Kruszewski (collectively "Plaintiff States"), and Stefan Kruszewski individually ("Plaintiff-Relator" or "Plaintiff-Relator Kruszewski"), state as follows in support of their *qui tam* Complaint against Defendant AstraZeneca Pharmaceuticals, LP:

I. INTRODUCTION

1. This action is based upon a scheme perpetrated by Defendant AstraZeneca Pharmaceuticals, LP ("AstraZeneca") to defraud the United States and the Plaintiff States (collectively the "Government Plaintiffs") by, *inter alia*, causing false claims to be submitted for AstraZeneca's atypical anti-psychotic Seroquel prescribed to patients and paid for by Medicaid and Medicare Part D or other publicly-funded health care programs.

A. Factual Background

2. Defendant AstraZeneca is the manufacturer of the potent #1 selling atypical antipsychotic prescription medication Seroquel. Seroquel is a second generation antipsychotic, also known as an atypical antipsychotic, FDA-approved to treat certain symptoms of Schizophrenia and Bipolar Disorder I, mental illnesses diagnosed in approximately 3.6 % of the United States population.

3. From the 1997 launch of AstraZeneca's "blockbuster" drug, AstraZeneca has

surreptitiously promoted Seroquel for a myriad of off-label uses and off-label patient demographics - particularly young children and the frail and infirm elderly - and has methodically misled the FDA, the Government Plaintiffs, the medical community and the public about the comparative safety, efficacy and superiority of Seroquel over alternative available medications. To AstraZeneca's knowledge and contrary to its promotional rhetoric, however, Seroquel is no more effective than far cheaper available alternative medications and, even if the drug is prescribed for FDA-approved uses, causes patients to develop serious, oftentimes irreversible and even lethal medical complications including treatment-emergent diabetes type II and other conditions relating thereto, including dramatic weight gain, cardiovascular and cerebrovascular injuries and initiation or worsening of metabolic syndrome.

4. AstraZeneca embarked upon this course of unlawful conduct knowing it would lead to the submission of a myriad of claims for Seroquel by Medicare and Medicaid-participating pharmaceutical providers, when by law these claims were not reimbursable and would not have been reimbursed by the Medicaid and Medicare programs of Plaintiff Governments had the truth about AstraZeneca's illegal marketing scheme, based upon misinformation and misrepresentations about Seroquel, been known.

5. AstraZeneca's fraudulent advertising, marketing and promotion of Seroquel succeeded in exponentially increasing its profits by generating incredible demand and consumption of Seroquel. AstraZeneca entered into corrupt political alliances that created a vast publicly-funded market of Seroquel consumers. AstraZeneca used, *inter alia*, bogus clinical studies, continuing medical education seminars and other marketing schemes to ensure that medical professionals prescribed Seroquel as a first line of

treatment for patients presenting with a litany of mental disorders. Consequently, Seroquel has overtaken it competitors for the lead in the $10.5 billion US market for atypical antipsychotics, capturing a 24.8% share of that market in 2005. More telling, AstraZeneca's relentless off-label promotions catapulted Seroquel to 20th place on the Bloomberg News Ranking of world's best selling prescription drugs in 2005. Such an achievement would be inconceivable absent AstraZeneca's illegal off-label scheme considering Seroquel is FDA-approved to treat a mere 3.6% of the United States population.

6. Given the predominant consumption of antipsychotics by beneficiaries of public health insurers, AstraZeneca's advertising and promotional scheme has caused devastating and unnecessary economic burdens on publicly-funded health plans, such as Medicare and Medicaid. These plans have improperly paid hundreds of millions of dollars for ineligible claims for Seroquel prescriptions each year. Compounding the financial impact of the profound rise in the number of Seroquel claims improperly caused by AstraZeneca to be presented to the Government Plaintiffs for payment, Seroquel unit monthly costs are hundreds of dollars more per prescription than alternative antipsychotic medications – such as the equally effective first generation antipsychotics.

7. The facts alleged herein, based upon the medical expertise and first-hand knowledge of the Plaintiff-Relator, demonstrates AstraZeneca's dissemination of fraudulent statements, duplicitous conduct, and pervasive false and misleading marketing, advertising and promotional schemes throughout the United States. AstraZeneca's outrageous conduct of marketing misinformation about the safety and efficacy of Seroquel to boost sales of their drugs that has induced massive purchases of Seroquel

subsidized by the Government Plaintiffs, has and continues to violate the Federal False Claims Act (the "FCA") and the analogous laws of the Plaintiff States. The FCA and the laws of the Plaintiff States permit any person discovering a fraud perpetrated against the Government to bring an action for himself and for the Government and to share in any recovery. Accordingly, Plaintiff-Relator commences this *qui tam* action individually and on behalf of the Government Plaintiffs against Defendant AstraZeneca seeking civil penalties and treble damages for AstraZeneca's violations of the False Claims Act 31 U.S.C. §§ 3729-3730 commensurate with the gravity of the harm AstraZeneca has caused to the public, as well as civil penalties and damages available under the laws of the California, Delaware, Florida, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Mexico, Tennessee, Texas, Virginia and the District of Columbia.

b. Plaintiff-Relator's Background

8. Plaintiff-Relator Stefan Kruszewski, M.D. is a clinical/academic psychiatrist licensed to practice medicine in six states – Pennsylvania, New Jersey, Texas, California, Nebraska and Indiana - and is authorized pursuant to his licensure to prescribe prescription drugs by the Drug Enforcement Agency. Plaintiff-Relator is and/or has been certified by the American Board of Psychiatry and Neurology in general and psychiatric subspecialties, by the American Society of Addiction Medicine and by the American Board of Adolescent Psychiatry.

9. Plaintiff-Relator's solo-authorship works have been published in numerous respected peer review medical journals such as the *New England Journal of Medicine, American Journal of Psychiatry, Archives of Neurology, British Medical Journal (BMJ),*

and Journal of the American Medical Association (JAMA; as of September 13th, 2006) – just to name a few.

10. Plaintiff-Relator Kruszewski has extensive personal experience providing psychiatric care to beneficiaries of various states Medicaid and federal Medicare programs, including the Commonwealths of Pennsylvania and Massachusetts and the states of Texas, New Jersey and New Hampshire. In his private practice, Plaintiff-Relator has treated patients and/or reviewed patient files of individuals who rely upon Government-funded health plans to pay for their necessary prescription drugs and have been caused to suffer severe medical complications resulting from Seroquel therapy that AstraZeneca intentionally hid from the public. Significantly, Plaintiff-Relator has personal experience with the efficacy, safety and adverse event profile of the antipsychotic drug class since he has prescribed the less expensive first generation antipsychotics, as well as second generation antipsychotics, including Seroquel, to his patients. Having discovered the fraudulent practices of AstraZeneca, he continues to prescribe Seroquel to his patients only because he possesses the essential information about the dangerous attributes of Seroquel that AstraZeneca intentionally hid from the medical community enabling him to make sound, patient-specific medical judgments in regard to the risk-reward analytic assessment of prescribing Seroquel.

11. From 2001-2003, Plaintiff-Relator was employed as the psychiatric medical consultant for the Pennsylvania Department of Public Welfare. In this position he served dual roles. In one capacity, he evaluated the quality of care for purposes of reimbursement. In the second, he was the only adult psychiatrist working at the Bureau of Program Integrity (the "BPI"). The BPI is a mandatory program that, pursuant to its

mission statement, was implemented to root out fraud, waste and abuse so that neither the federal dollars that funded the Pennsylvania Medicaid program (slightly over 56%) nor the state funding contribution (about 44%) would be forced to pay for unnecessary, inferior or substandard care. In the course of his employment, Plaintiff-Relator identified the waste of scarce public funds caused by gross over-utilization of Seroquel improperly prescribed off-label to treat young children diagnosed with afflictions completely unrelated to Seroquel's tested and approved uses.

12. Plaintiff-Relator has also directly witnessed the unscrupulous marketing tactics of AstraZeneca. AstraZeneca and other atypical antipsychotic drug manufacturers have retained Plaintiff Relator Kruszewski to promote their drugs in presentations before peers, for which he would earn the premium industry standard fees of up to $1500 per appearance. In connection with his retention by AstraZeneca to speak about and promote Seroquel, AstraZeneca provided Plaintiff Relator with a prepackaged slide show. Plaintiff Relator discovered based upon his medical expertise that the slide show contained materially false and misleading information about Seroquel's efficacy for indicated and non-indicated prescribing, yet AstraZeneca mandated that Plaintiff Relator use the deceptive slide show as the sole content of his Seroquel presentation. Admirably opting to adhere to medical ethics over financial gain – an all too infrequent occurrence - Plaintiff-Relator declined to accept such lucrative speaking engagements on behalf of AstraZeneca.

II. JURISDICTION AND VENUE

13. This court has jurisdiction over the subject matter of this action: (i) pursuant to 31 U.S.C. §3732 and 31 U.S.C. § 3730(b), which specifically confers jurisdiction on

this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730; (ii) pursuant to 28 U.S.C. §1331, which confers federal subject matter jurisdiction; and (iii) pursuant to 28 U.S.C. §1345, because the United States is a plaintiff.

14. Plaintiff Kruszewski has direct and independent knowledge of the information upon which the allegations are based and has voluntarily provided notice of this action to the government before filing this *qui tam* action.

15. Plaintiff-Relator Kruszewski shall provide to the Attorney General of the United States and to the United States Attorney for the Eastern District of Pennsylvania a statement summarizing known material evidence and information related to this Complaint, in accordance with the provisions of 31 U.S.C. §3730(b)(2). This disclosure statement is supported by material evidence.

16. This court has jurisdiction over AstraZeneca under 31 U.S.C. §3732(a) because Defendant AstraZeneca can be found in, is authorized to transact business in, and is now transacting business in this District. In addition, acts proscribed by 31 U.S.C. §3729 have occurred in this District.

17. Venue is proper in the Eastern District of Pennsylvania because AstraZeneca conducts business in this District and, upon information and belief, acts giving rise to this action occurred within this District.

III. PARTIES

18. Plaintiff-Relator Kruszewski is a citizen and resident of the Commonwealth of Pennsylvania. He brings this action on his own behalf and on behalf of the federal and state governments pursuant to 31 U.S.C. §3730(b)(1) for false and fraudulent claims submitted to federally-and state-funded government programs, including Medicaid and

Medicare.

19. Defendant AstraZeneca is a Delaware limited partnership with a principal place of business located in Wilmington Delaware. AstraZeneca does business in Pennsylvania by distributing, marketing, selling and profiting from Seroquel throughout the entire United States, including the Commonwealth of Pennsylvania. Defendant AstraZeneca can be served with original process in Pennsylvania at CT Corporation System, 1515 Market Street, Suite 1200, Philadelphia, PA 19102. Defendant AstraZeneca is the US subsidiary of AstraZeneca, PLC, which has corporate headquarters located in the United Kingdom and Research and Development headquarters located in Sweden.

IV. THE FEDERAL AND STATE FALSE CLAIMS ACTS

20. The False Claims Act, 31 U.S.C. §§ 3729 to 3733, provides, in pertinent part, that:

> (a) Liability for certain acts. Any person who--
>
> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;
>
> (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;
>
> (b) Knowing and knowingly defined. For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information--
>
> (1) has actual knowledge of the information;

(2) acts in deliberate ignorance of the truth or falsity of the information; or

(3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

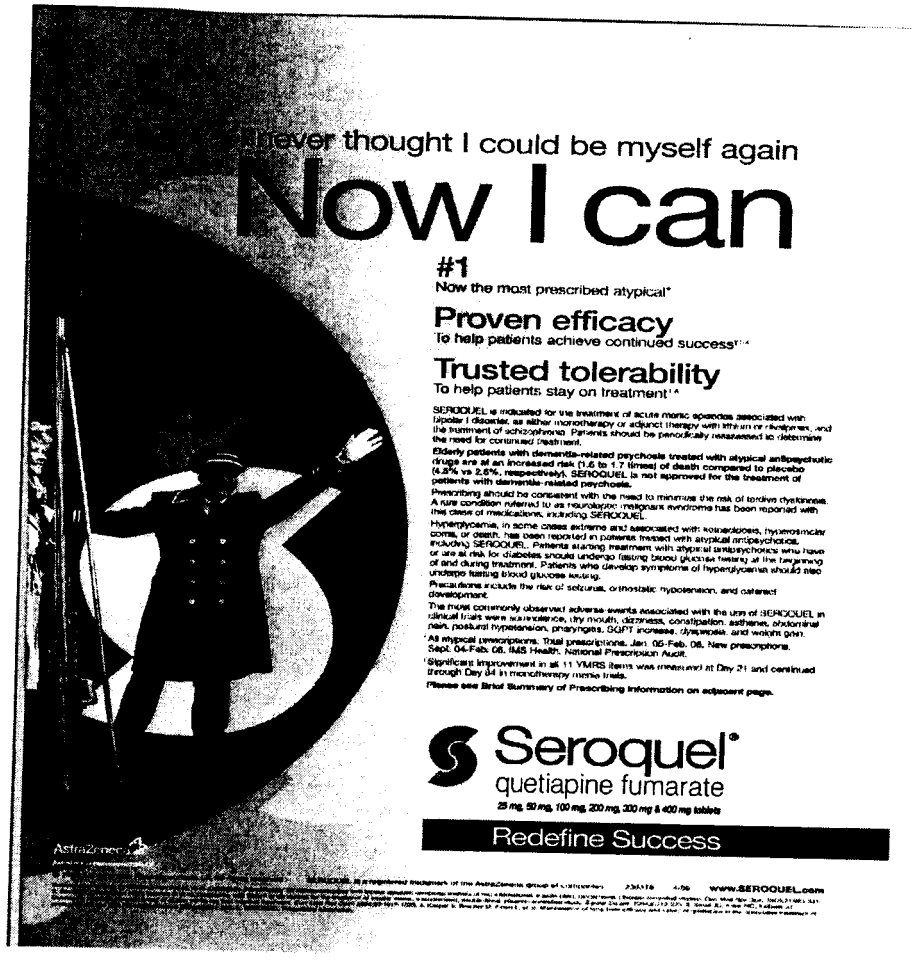
31 U.S.C. § 3729.

21. To cover the Plaintiff States' share of Medicaid spending, the Plaintiff States enacted laws modeled after the Federal False claims Act (collectively the "Plaintiff States' False Claims Acts"). The Plaintiff States' False Claims Acts mirror the broad proscriptions of the Federal False Claims Act, including those set forth in §§3729 (a)(1), (2), (3) and (7). See *e.g.* Montana False Claims Act, §3(1)(a), (b), (c) and (g); Illinois Whistleblower Reward and Protection Act, § 3(a)(1), (2), (3) and (7); Virginia Fraud Against Taxpayers Act, § 8.01-216.3 A(1), (2), (3), and (7); Indiana False Claims and Whistleblower Protection, § IC 5-11-5.5-2B (7) and (8); Nevada Submission of False Claims to State or Local Government, 357.040 (1)(a), (b), (c), and (g).

22. A pharmaceutical company is liable under the Federal False Claims Act and analogous state laws, where as here, its unlawful promotional practices and representations mislead healthcare providers into prescribing a drug and submitting reimbursement claims for such prescriptions to Medicare, Medicaid and other federal and/or state health insurance programs.

23. At all times relevant to the complaint, AstraZeneca has engaged in marketing efforts calculated to dupe, *inter alia*, physicians and pharmacists into favoring Seroquel over other prescription drugs for on and off-label uses by misrepresenting Seroquel's superior comparative efficacy and low incidence of side effects, knowing that the ultimate payer for these prescriptions would be publicly-funded health plans such as

Medicaid and Medicare. By way of example, AstraZeneca bombarded the medical community with misleading advertisements such as the following sanguine, full page, brightly colored advertisement on page 15 in the respected journal *Psychiatric News*, May 5th, 2006. *Psychiatric News* is the official publication of the American Psychiatric Association:



24. Plaintiff-Relator's analysis of the studies AstraZeneca cites in support of its representations of "Proven efficacy" and "trusted tolerability" in large bolded print has demonstrated that they do not substantiate AstraZeneca's claims. Rather, this advertisement conforms to AstraZeneca's pattern and practice of unsubstantiated

exaggeration of the safety and efficacy of Seroquel.

25. By and through this type of deceptive conduct, AstraZeneca has caused false statements and claims for Seroquel to be submitted to the Government Plaintiffs. Plaintiff-Relator, in the name of the United States and the Plaintiff States as detailed herein, seeks to hold the Defendant Manufacturers liable for knowingly causing false claims to be presented for payment and for conspiring to bilk tremendous revenues from public funds.

VI. GOVERNMENT-FUNDED PRESCRIPTION DRUG PROGRAMS

A. The Medicaid Program

26. Title XIX of the Social Security Act is a program which provides medical assistance for certain individuals and families with low incomes and resources. The program, known as Medicaid, became law in 1965 as a jointly funded cooperative venture between the Federal and State governments to assist States in the provision of adequate medical care to eligible needy Americans. Among the groups of people served by Medicaid are eligible low-income parents and children.

27. Nationwide, state Medicaid programs have annually purchased an estimated 60 to 75 percent or more of antipsychotic drugs, including Seroquel, at all times relevant to this complaint.

28. For example, California's Medicaid program known as Medi-Cal paid an extraordinary $142.3 million for its beneficiaries' Seroquel prescriptions in just a one year period – from July 1, 2004 to June 30, 2005.

29. The Medicaid Program (42 U.S.C. § 1395, *et seq.*) is administered through the Centers for Medicare and Medicaid Services (CMS), which is a division of the

Department of Health and Human Services (HHS) of the federal government. Numerous states statutorily limit Medicaid reimbursement for prescription drugs to those uses approved by the FDA or when the prescribing physician makes a medical necessity certification after the identified patient has failed to respond to treatment with medications indicated for the patient's illness. This prohibition directly implicates AstraZeneca's off-label marketing scheme because claims for off-label prescriptions were induced to be submitted to the Government Plaintiffs for reimbursement without the required certification of medical necessity.

B. ***The Medicare Part D Program***

30. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"). Title I of the MMA created new outpatient prescription drug coverage under Medicare ("Medicare Part D"). Medicare Part D went into effect on January 1, 2006. The Program is administered by the United States Department of Health and Human Services, Centers for Medicare and Medicaid ("CMS").

31. For "dual eligibles" defined as individuals who received prescription drug coverage under Medicaid in addition to Medicare coverage for other health care in 2005, enrollment in Medicare Part D was compulsory. These beneficiaries were *automatically* switched to Part D plans for 2006 and commenced receiving comprehensive prescription drug coverage under Medicare Part D.

32. As of June 2006, more than 20 million individuals had enrolled in and are receiving prescription drug benefits through the Medicare Part D program.

33. Financing for the Part D prescription drug benefit comes from state

contributions, the federal government and premiums paid by beneficiaries,

34. The Medicare Part D formulary includes Seroquel as a covered drug the cost of which is eligible for reimbursement under appropriate medical circumstances.

35. Accordingly, since January 1, 2006, the Government Plaintiffs have paid for prescriptions of Seroquel, in whole or in part, through the Medicare Part D program, which were unlawfully induced to be written by AstraZeneca's marketing campaign, and therefore constitute false claims.

VI. THE REGULATORY ENVIRONMENT

36. The pharmaceutical industry is highly regulated by the Food and Drug Administration ("FDA"). Pursuant to the Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq.*, the FDA determines which drugs may be promoted and sold in the United States and strictly regulates the content of consumer and physician based advertising, direct-to-physician product promotion, and drug labeling information used by pharmaceutical companies in promoting and selling FDA approved prescription drugs.

A. FDA Regulation of Sales, Labeling and Promotional Activities of Drug Manufacturers.

37. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-397, pharmaceutical drugs cannot be marketed for sale in the United States unless the drug's manufacturer obtains approval of the drug from the Food and Drug Administration ("FDA"). Based upon efficacy and safety studies submitted by drug companies in support of a "New Drug Application" - an inherent flaw in the system - the FDA renders a determination whether the submitted information is consistent with its regulatory guidelines for approval, *i.e.*, that the drug is safe and effective for each of its intended uses when administered at specified dosages. 21 U.S.C. §355(a) and (d).

38. A drug's FDA-approved uses and dosages are called the drug's "indication." A drug's indication is set forth in the drug's labeling. An example of the drug's labeling is the printed insert contained in the drug's packaging. Under 21 C.F.R. § 202.1(k)(2), drug manufacturers' marketing and promotional materials related to the drug aimed at physicians, *i.e.*, all brochures, handouts, slide shows or other such promotional materials, are also deemed to be "product labeling" and are regulated as such. By law, representations made in any labeling material must be truthful, not misleading and represent a fair balance of the information presented. Any failure to fairly and accurately represent the required information about a prescription drug is considered misbranding and is a false and fraudulent statement as a matter of law. *See* 21 U.S.C. §§ 331(a) and (b), 352(a), (f) and (n); 21 C.F.R. § 201.57.

39. Thus, under relevant FDA regulations, product labeling must be pre-approved by the FDA and conform to very exacting requirements concerning, *inter alia*, drug interactions, indicated uses and claims concerning competing products. *See* 21 C.F.R. § 201.57. A drug's labeling must therefore include adequate warnings about the drug. These warnings include the full and fair disclosure of known contraindications, side effects and effectiveness. The adequacy of the warnings set forth in the drug's labeling is instrumental to the practice of medicine in that the label and its warnings are relied upon by healthcare providers to make sound medical decisions in order to prescribe the safest and most effective medication available to treat their patients' conditions.

40. Pharmaceutical promotional and marketing materials and presentations lacking in fair balance or that are otherwise false or misleading violate the Food Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated hereunder. Such

violations exist where promotional and marketing materials and presentations for an FDA approved drug:

a) Minimize, understate or misrepresent the risks, contra-indications and complications associated with that drug;
b) Overstate or misrepresent the risks, contra-indications and complications associated with any competing drugs;
c) Reference "off label" uses, described *infra*, of the drug for which it was not an approved indication by the FDA, or expressly or implicitly promote unapproved uses and dosing regimens for which the drug is not indicated;
d) Make comparative claims about the drug that have not been demonstrated by substantial evidence, such as comparisons with competing drugs and/or drug indications of patient usage, warnings and safety claims including side effects, physician preference; or,
e) are otherwise false, misleading or lacking in fair balance in the presentation of information about the drug being marketed or any competing drug.

41. AstraZeneca materially violated these clear cut labeling and misbranding regulations by intentionally overstating the comparative efficacy of Seroquel and by concealing its prolific side effects in, *inter alia*, Seroquel's deficient package inserts and in direct-to-physician marketing. AstraZeneca's distorted science and illegal misbranding of Seroquel was intended to and did fraudulently induce primary care physicians, neurologists and psychiatrists to prescribe Seroquel without knowing the adverse consequences of the prescription upon their patients' health and to submit claims for reimbursement for Seroquel prescriptions to publicly-funded health plans such as Medicare and Medicaid. Each such claim AstraZeneca knowingly induced to be submitted under these false pretenses in derogation of the labeling and misbranding laws constitutes a false claim for which it accountable under the Government Plaintiffs' false claims acts.

B. The Law Prohibits Drug Manufacturers from Engaging in Off-Label Marketing To Protect the Health and Safety of Prescription Drug Consumers

42. "Off-label" prescribing of drugs occurs when a drug is used by a medical professional beyond the drug's indication. This includes prescribing a drug for a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or to treat a different patient population (*e.g.* treating a child with the drug when the drug is approved to treat adults).

43. Pursuant to the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), an off-label use of a drug can cease to be off-label only if the manufacturer conducts studies and submits a new drug application demonstrating to the satisfaction of the FDA that the product is safe and effective for the proposed new use or uses. 21 U.S.C. §360aaa(b) and (c).

44. Off-label marketing by pharmaceutical companies is closely regulated by the FDA and the law. These regulations protect patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an ostensibly independent, scientific governmental body, the FDA.

45. Under the Food and Drug laws, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose, and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. Drug manufacturers are prohibited from actively marketing or promoting a drug for any unapproved indication, as alleged *supra*.

46. In addition to prohibiting manufacturers from directly marketing and promoting a product's off-label uses, Congress and the FDA have also prohibited manufacturers from employing indirect methods to accomplish the same end.

47. Specifically, Congress and the FDA have promulgated laws designed to regulate two of the most prevalent indirect promotional strategies: (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products, and (2) manufacturer support for Continuing Medical Education ("CME") programs that focus on off-label uses of their drugs.

48. With regard to the first practice – disseminating written information – the FDAMA permits a manufacturer to disseminate information regarding off-label usage *only* in response to an "unsolicited request from a health care practitioner." 21 U.S.C. §360aaa-6 (emphasis added). In any other circumstance, that manufacturer cannot disseminate information concerning the off-label uses of a drug unless: (1) the manufacturer has submitted an application to the FDA seeking approval of the drug for the off-label use; (2) has provided the materials to the FDA prior to dissemination; and (3) the materials themselves must be in an unabridged form and must not be false or misleading. 21 U.S.C. §360aaa(b) & (c); 360aaa-1.

49. With regard to the second practice --- manufacturer involvement in CME programs--- the FDA's examination of these practices led to publication of an agency enforcement policy in 1997 titled, "Guidance for Industry: Industry-Supported Scientific and Educational Activities." 62 Fed. Reg. 64,074, 64,093, 1997 WL 740420 (F.R.)(1997). This guidance document states that CME programs must be truly independent of the drug companies, and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias." *Id.* The promotion of off-label drug uses at a CME program which fails the test of "independence" violates Congress' off-label marketing restrictions.

50. Although physicians are not prohibited from prescribing an FDA-approved drug "off-label" based upon their fully informed, independent medical judgment, as alleged *supra*, pharmaceutical promotional and marketing materials and presentations are false or misleading in violation the Food Drug and Cosmetics Act and regulations promulgated hereunder if they advertise "off label" uses of a drug, or expressly or implicitly promote unapproved uses and dosing regimens for which the drug is not indicated.

51. Placing profits ahead of the law, AstraZeneca relentlessly targeted children and elderly with its dangerous and illegal "off-label" marketing, promotional and advertising campaign for Seroquel, resulting in an extreme undue financial burden foisted upon the publicly-financed health system. This is the very conduct the Government Plaintiffs' false claims acts were promulgated to redress.

VII. ASTRAZENECA'S FRAUDULENT SEROQUEL MARKETING CAMPAIGN

A. FDA-Approval of Seroquel

52. In June 1997, AstraZeneca obtained FDA-approval for Seroquel for three (3) narrowly defined indications: 1) the treatment of *acute* manic episodes associated with bipolar I disorder in adults, including with the combined use of lithium and/or valproate; 2) the acute treatment of schizophrenic psychoses in adults and 3) to be administered in dosages of either 50 mg, 100mg or 200mg. Since the drug's approval, AstraZeneca has widely advertised, marketed, dispensed and sold Seroquel.

53. Bipolar disorder I, a condition marked by mood swings between euphoria/mania and depression, affects approximately 2.1 million Americans. Approximately 2.4 million Americans have been diagnosed with schizophrenia. Because

of the chronic nature of these indicated diagnoses, Seroquel is prescribed as a long-term drug therapy because it is purported to work by having a broad effect on certain cortical neurotransmitter receptors (special chemical communicators in the central nervous system), including dopamine and serotonin receptors, that are thought to mediate acute symptoms of mania and psychosis.

54. As a matter of the elemental economic theory of supply and demand, a drug indicated to treat less than 3.6% of the population cannot generate annual sales of more than a billion dollars annually, absent unlawful off-label promotion. Accordingly, AstraZeneca introduced Seroquel onto the market for the purpose of ultimately being prescribed for off-label uses in addition to FDA-approved indications in order to maximize its financial gain knowing that publicly-funded health programs such as Medicaid and Medicare would be the primary purchasers of such prescriptions for its beneficiaries.

B. AstraZeneca Jeopardized Patient Safety by Concealing Seroquel's Known Side Effects To Maximize its Financial Gains.

55. Upon their introduction to the market, the "new generation" of atypical antipsychotics – known as a class as "second generation antipsychotics" – were touted by their drug manufacturers as being safer, more effective and relatively free of most side effects as compared to the older, first generation antipsychotics. To the contrary, Seroquel is not safer or more effective than first generation antipsychotics; Seroquel simply has a ***different*** side-effect profile which includes both a severe metabolic syndrome and cardiovascular problems, while still causing neurological side effects like the older typical antipsychotics.

56. Specifically, among the known, but surreptitiously hidden side-effects of

Seroquel is an unacceptably high rate of irreversible treatment-emergent diabetes type II onset. In fact, Seroquel is nearly 3.4 times more likely to cause diabetes than first generation antipsychotics such as haloperidol. The risk of treatment-onset diabetes with Seroquel also compares unfavorably to several competing second generation antipsychotics. Seroquel patients who develop diabetes additionally suffer from a host of diabetic complications, which require regular medical monitoring, medical treatment and care. Such complications substantially increase the cost of care to treat these side effects which must be funded by insurers, including Medicaid and Medicare.

57. AstraZeneca was also aware that Seroquel produced and/or aggravated other related and dangerous treatment-emergent side effects such as obesity, hypertension, cardiovascular complications, heart attacks and stroke.

58. AstraZeneca's widespread claims of safety and efficacy made to the FDA, physicians, and consumers were intended to conceal the host of deadly side effects associated with Seroquel. AstraZeneca was aware Seroquel caused a high occurrence of diabetes, and other health complications, yet intentionally failed to take any measures to adequately warn doctors or patients in the United States of Seroquel's potential health risks to preserve Seroquel's astronomical sales.

59. AstraZeneca possessed knowledge that Seroquel caused these serious side effects through the adverse event reporting system and its own Seroquel studies withheld from the public eye. AstraZeneca knew this even before it sought FDA approval of the drug. Knowing the disclosure of such negative data would doom Seroquel sales, AstraZeneca not only concealed the existence of such side effects while continuing to aggressively market Seroquel as safe and effective for its indicated uses.

60. AstraZeneca failed to disclose these known side effects in Seroquel's package insert and promotional materials. Nor did AstraZeneca's sales representatives disclose these side effects in sales calls to prescribing physicians.

61. Rather, after years of denying Seroquel's side effects, the FDA forced AstraZeneca in September 2003 to disclose the link between Seroquel and diabetes and other related side effects by requiring AstraZeneca and the other makers of atypical antipsychotics to add to their labels a warning that the drugs can cause hyperglycemia, diabetes, and even death.

62. AstraZeneca immediately launched a campaign to deflect blame for these serious side effects away from Seroquel to the *diseases* Seroquel is indicated to treat. Specifically, AstraZeneca began advancing the misleading statement in literature supported with junk Astra-Zeneca-sponsored science that individuals who suffer from mental illnesses such as schizophrenia and bipolar disorder are *predisposed*, *i.e.*, have a heightened incidence of diabetes, metabolic syndrome, cardiovascular disease and premature mortality compared to the general population.

63. AstraZeneca contrived this "blame the disease not the drug" campaign knowing it was materially false and not supported by valid science.

64. As a result of AstraZeneca's intentionally misleading marketing campaign, beneficiaries of health plans funded by the United States, the Plaintiff States and private insurers were prescribed Seroquel when safer and less expensive alternative medications would have been the preferred course of therapy had AstraZeneca disclosed fair and balanced information about Seroquel's hidden dangers. As a result, pharmacies were induced to fill these Seroquel prescriptions and then to submit claims to the Government

and private insurers seeking reimbursement for the cost of Seroquel therapy. Such claims were paid because the Government was unaware that AstraZeneca's Seroquel marketing campaign, which caused these claims to be submitted for payment, was materially false and misleading.

65. AstraZeneca's fraud caused public and private insurers that fund prescription drug therapy to suffer dramatic increases in their expenditures. The cost of therapy would have been far less had beneficiaries been prescribed cheaper and similarly effective first generation antipsychotics, such as haloperidol or perphenazine.

C. In Derogation of the Law, AstraZeneca Unlawfully Marketed Seroquel Off-Label As Safe and Effective to Treat the Elderly, Children, and Non-Indicated Symptoms

66. Drug development is a long and costly affair. In many cases, once a drug has won patent approval and its clinical trials have garnered the nod from the FDA, researchers will discover that the drug is useful in treating other illnesses. Given the length and cost of getting a drug approved for such newly discovered uses, particularly in light of the limited duration of a drug's patent-protection, drug manufacturers are financially incentivized to circumvent this process and simply market the drug for non-indicated uses, even though this practice is strictly prohibited by law.

67. AstraZeneca far surpassed the limited leeway it had under the law to promote off-label uses of Seroquel. It is no accident that AstraZeneca boasts Seroquel has at least 16 million patient exposures worldwide.

68. AstraZeneca engaged in this illegal campaign for several reasons. First, AstraZeneca concluded that it would be uneconomical to assume the expense and time necessary to conduct clinical trials to prove that Seroquel was "safe and effective" for

off-label uses. Indeed, even if the research were successful, and the off-label uses were shown to be safe and effective, AstraZeneca's patent would soon expire and generic manufacturers would reap much of the reward of proving Seroquel could be safely used for other indications. By promoting Seroquel for "off-label" uses that have not been found to be safe and effective by the FDA off-label drugs surreptitiously, AstraZeneca expanded its product's market without the expense usually associated with such an endeavor. Moreover, AstraZeneca's strategy had an additional advantage – it could be launched immediately; there was no need to wait for the results of scientifically conducted clinical trials to determine if Seroquel was actually effective in the treatment of off-label conditions.

69. Putting profits ahead of patient safety, AstraZeneca has recklessly exaggerated the efficacy of Seroquel to treat patient populations beyond the drug's indications and has downplayed and/or intentionally concealed the high incidence of Seroquel's dangerous and even life-threatening treatment-emergent side effects, contraindications and adverse reactions from physicians, pharmacists and the public at large since 1997. AstraZeneca acted with actual knowledge that its illegal off-label promotional activities and misbranding of Seroquel would result in false claims being submitted to the Government, or at a minimum, AstraZeneca acted with reckless disregard or deliberate indifference thereof.

70. As detailed herein, the fraudulent scheme not only caused substantial monetary damage to the federal and state governments that were improperly deceived into reimbursing claims for Seroquel prescriptions, but also caused many elderly and pediatric patients to suffer unnecessary pain and serious, irreversible medical

complications because of the unproven efficacy of the potent antipsychotic and the undisclosed side effects known by AstraZeneca to be caused by the drug.

71. Children and the elderly – AstraZeneca's target off-label market - largely rely upon Medicaid and Medicare to pay for their prescription needs. They are also large consumers of prescription medications, making successful penetration into the off-label market for these groups particularly profitable. This conduct was particularly outrageous given the fragility of the elderly and children and their acute susceptibility to side effects.

72. AstraZeneca launched an off-label marketing campaign promoting Seroquel as safe and effective to treat young children diagnosed with a variety of disorders such as autism, attention-deficit/hyperactivity disorder, conduct disorder, adolescent mania, mood disorders and other behavioral problems. The majority of these Seroquel prescriptions have been induced by AstraZeneca to be written for children *who have not even been diagnosed with a psychotic disorder*, much less schizophrenia or bipolar I disorder. In fact, the average age of onset for schizophrenia and bipolar disorder I is not until the late teens, or even later.

73. Plaintiff-Relator Kruszewski has personal knowledge, from his work in a peer review capacity for the Commonwealth of Pennsylvania and elsewhere, that Seroquel prescriptions were written for many conditions in which individuals were neither psychotic nor demonstrated the manic symptoms or mixed symptoms of bipolar I disorder but, instead, were being medicated with an antipsychotic agent with sedative properties in order to induce sleep, as an anti-anxiety agent, to "medicate" oppositional and defiant behavior in children and adolescents, for depressive syndromes, for aggression, for episodes of behavioral acting out and for specific phobias, as well as post-

traumatic stress disorder.

74. Furthermore, expensive long term Seroquel therapy for children took the place of the far cheaper drug therapy with Haldol **which is FDA-approved for use in children under the age of 18**, unlike Seroquel.

75. Plaintiff-Relator also has personal knowledge gained from treating patients and reviewing patient medical records of the disastrous, undisclosed side-effects that pediatric patients have suffered as a direct and proximate result of being prescribed this potent atypical antipsychotic.

76. AstraZeneca also illegally marketed Seroquel for geriatric patients suffering from insomnia and dementias such as Alzheimer's disease. Remarkably, even AstraZeneca admits on its Seroquel website: "Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared with placebo. SEROQUEL is not approved for the treatment of patients with dementia-related psychosis." *See* www.seroquel.com.

77. This admission was obviously prompted by the FDA's issuance of a public health advisory on April 11, 2005 to alert health care providers, patients, and patient caregivers, a determination based upon clinical studies, that the treatment of behavioral disorders in elderly patients with dementia with Seroquel and the other atypical antipsychotic medications is associated with increased mortality. Examination of the specific causes of these deaths revealed that most were either due to heart related events (e.g., heart failure, sudden death) or infections (mostly pneumonia). Accordingly, the FDA required AstraZeneca to amend Seroquel's label to include a "black box warning" of this deadly side effect.

78. A 'black box' designation is an FDA-recommended/mandated warning based upon clinical research studies, for certain drugs that may cause serious and potentially life-threatening side effects. The FDA requires that a black box warning be placed on the labeling or literature of a prescription drug, or in literature describing it. It is the strongest warning that the FDA requires.

79. To further expand the market share of Seroquel, AstraZeneca exploited its knowledge that some symptoms of Schizophrenia and Bipolar Disorder I overlap with other illnesses. Accordingly, AstraZeneca skirted the off-label marketing regulations by devising a marketing campaign focused on Seroquel's efficacy in treating a variety of common *symptoms* relating to mood and behavioral disturbances, such as depression, agitation, sleeplessness and anxiety. By promoting Seroquel's purported effectiveness in treating vague cross-over symptoms, physicians were induced to make Seroquel one of their routinely used prescription medications for patients who had not been diagnosed with bipolar disorder I or schizophrenia. Accordingly, Seroquel is routinely prescribed off-label to patients of all ages to treat a number of symptoms including personality disorder, depression, anxiety, agitation, insomnia and migraine headaches, when there is no science to support prescribing such a potent drug for conditions that could be successfully treated by other therapies without the substantial health risks posed by Seroquel. Yet, the unwitting victims of AstraZeneca's fraud are suffering serious health complications and even dying from Seroquel's hidden side effects at alarming rates all at the expense of scant public funds.

80. Indeed, as of the date of filing this complaint, 1329 deaths have been reported to the US FDA by physicians who believed that Seroquel was the cause of, or related to,

the death reported. Reporting is voluntary, not compulsory; however, therefore the number of Seroquel-related deaths is likely to be much higher.

81. Had the Government Plaintiffs' known of AstraZeneca's pervasive fraud, they would not have subsidized the purchase of Seroquel for these dangerous, untested off-label uses.

D. AstraZeneca Uses Improper Funding to Forge a Corrupt "Political/Pharmaceutical Alliance" to Increase the Market Share of Seroquel in Large, State-Operated Mental Health Institutions.

82. AstraZeneca has directed its deceptive marketing practices towards corrupting state officials to capture the government's lucrative Medicaid and Medicare markets by "promoting" their drugs through payoffs to state officials who control the drugs prescribed to patients of large public systems who suffer from serious mental illness. Those patients -- in state mental hospitals, prisons, government-funded mental health clinics -- are typically beneficiaries of the Medicaid or Medicare Part D programs, making the Plaintiff United States and the Plaintiff States among the largest buyers of antipsychotic drugs.

83. As a result of this marketing strategy, sales of Seroquel and other atypical antipsychotics have soared in a population whose prescription drug coverage is known to be funded by the Government, primarily through Medicaid and Medicare.

84. Among other things, AstraZeneca has paid considerable financial remuneration to influence prescribing practices of these public institutions by funding the implementation of guidelines, or algorithms, which dictate the medication treatment regimen for those diagnosed with different psychiatric conditions in the care of the aforementioned public institutions. One such algorithm is TMAP -- the Texas

Medication Algorithm Project.

85. TMAP arose from a corrupt alliance that began in 1995 between the pharmaceutical industry, the Texas Department of Mental Health and Mental Retardation (TDMHMR), and the University of Texas-Southwestern Medical School. The project was funded by a Robert Wood Johnson grant—and by several drug companies, including AstraZeneca.

86. TMAP is a decision-tree medical algorithm. It provides a set of psychiatric management guidelines for doctors when treating patients diagnosed with certain mental disorders within Texas' publicly-funded mental-health care system, along with manuals relating to each disorder. The pharmaceutical treatment algorithms commence after diagnosis of a psychiatric illness, hence the name "Medication Algorithm." As a result, prescription treatment decisions specifying certain drugs are predetermined based upon a robotic, input/output basis – input the disease and the prescription treatment regimen is output, stripping away a physician's sound medical judgment to make prescribing decisions based upon the individual medical profile of his or her patients.

87. TMAP called for Seroquel and the other the newest, most expensive medications to be used as the first line of treatment for schizophrenia, bipolar disorder, and major depression in adults. This practice was expanded to the creation of an algorithm for treating children diagnosed with these conditions known as CMAP, although it has yet to be fully adopted by the state legislature.

88. At least nine states have adopted medication guidelines similar to TMAP and CMAP, and it is intended for the system to be implemented nationwide.

89. In exchange for having Seroquel receive high priority in the algorithm, *i.e.*,

being a first line of treatment for certain psychiatric diagnoses, thereby penetrating a vast market share involving thousands of prescriptions and millions of dollars in revenue, AstraZeneca provided substantial *unrestricted* funding for the project, purportedly for the creation of TMAP materials such as training materials and promotional videos. In reality, AstraZeneca has paid such substantial sums of money to obtain preferential positioning of Seroquel over competing drugs and in order to market that preferred status globally.

90. AstraZeneca paid money directly to the Texas Department of Mental Health and Mental Retardation (TDMHMR) to develop and expand the TMAP Algorithms. The March 4, 1999 MHMR minutes identify that has AstraZeneca donated $40,000 to the TMAP Project.

91. AstraZeneca also has made annual donations for several years to the TDMHMR Physician's Conference, the purpose of which is for physicians to fulfill their annual continuing medical education requirements. In truth, however, AstraZeneca and other drug companies have used these conferences as marketing opportunities to expand the penetration of their newly-developed, more expensive drugs into market segments.

92. As noted in the March 29, 2001 MHMR minutes, AstraZeneca donated $2500 for the 2001 TDMHMR Annual Physician's Conference.

93. As noted in the April 2002 MHMR minutes, AstraZeneca donated $750 for the 2002 TDMHMR Annual Physician's Conference.

94. As noted in the April 2003 MHMR minutes, AstraZeneca donated $6000 for the 2003 TDMHMR Annual Physician's Conference.

95. Upon information and belief, AstraZeneca's financial contribution to the

TDMHMR Conference runs afoul of the FDA's 1997 Industry-Supported Scientific and Educational Activities Guidance Document. As set forth in detail *supra*, the FDA's guidance document requires that CME programs must be free from a drug company's influence and bias and therefore, to the extent that the promotion of off-label drug uses at a CME program fails the test of "independence," the drug company is in violation of Congress' off-label marketing restrictions.

96. AstraZeneca also "donated" $7500 to the TIMA Project, as noted in the December 2002 MHMR minutes. The TIMA project was the Texas Implementation of TMAP. The purpose of this donation was to send psychiatrists like Steven Shon, MD to other states as an ambassador of the TMAP program for the purpose of expanding TMAP's implementation in other states as well as to provide training concerning the implementation and development of TMAP in these states. Again, these payments are nothing but a thinly-veiled attempt to filter extraordinary sums of money into the hands of those who can hand AstraZeneca market share for Seroquel.

97. To further entrench Seroquel's prevalence as the oft-prescribed, first line of treatment in the TMAP program, AstraZeneca set up numerous meetings and lunches in 2000, 2001, 2002 and 2003 with Stephen Shon, MD, the director of Texas MHMR. These meetings were designed to sell Seroquel to the Texas Department of Mental Health so that the drug would be heavily utilized in the Medicaid markets in Texas, and elsewhere.

98. AstraZeneca further influenced the TMAP Algorithms to increase utilization of Seroquel in the TMAP program by directly hiring numerous TMAP officials as AstraZeneca consultants and speakers and by funding their research grants, including:

- A. **John Rush, M.D.**, the University of Texas Southwestern Medical Center - Dallas: TMAP Project Director
- **M. Lynn Crismon, Pharm. D.,** the University of Texas at Austin College of Pharmacy: TMAP Project Co-Director
- **Patricia Suppes, M.D., Ph.D.**, the University of Texas Southwestern Medical Center - Dallas: Bipolar Disorder Module Director

E. AstraZeneca's Marketing Machine Has Driven Seroquel to Blockbuster Sales Status.

72. The success of AstraZeneca's fraudulent marketing tactics is made evident by the astronomical revenues Seroquel has generated despite Seroquel's limited indication.

73. Since 2004, Seroquel has annually achieved "blockbuster" sales status - defined in the industry as a drug that generates more than $1 billion of revenue for its manufacturer - in spite of the limited market for Seroquel's approved uses in the United States - merely 3.6% or less of the population of the United States.

74. The number of US prescriptions written for Seroquel has increased astonishingly since receiving FDA approval in 1997. The following tables chart the meteoric rise in prescriptions written for Seroquel in the United States from 1999 through 2004 and incredible revenues AstraZeneca gained therefrom.

Total U.S. Dispensed Scripts in Thousands (000)

Rank	**Drug**	**2004**	**2003**	**2002**	**2001**	**2000**	**1999**
Class Total		42,269	38,825	34,705	29,882	25,204	19,806
2	**Seroquel**	**10,624**	**8,186**	**6,108**	**4,184**	**2,649**	**1,386**

See http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_18731_63237611,00.html, dated July 17, 2006 (citing IMS Health, IMS National prescription Audit *Plus*™, 1/2005).

Total U.S. Sales $ in Thousands (000)

Rank	Drug	2004	2003	2002	2001	2000	1999
Class Total		$9,053,841	$8,053,072	$6,619,177	$5,374,591	$4,035,986	$3,162,914
3	**Seroquel**	**$1,978,618**	**$1,507,098**	**$1,090,417**	**$703,666**	**$423,493**	**$223,653**

*Source: IMS Health, IMS National Sales Perspectives™, 1/2005

75. According to AstraZeneca's Annual Report and Form 20F Information for 2005, Seroquel's sales surged to $2.76 billion in 2005 and "further strengthened its position as the most prescribed atypical antipsychotic in the United States." This trend continued into 2006 as AstraZeneca reported that sales of Seroquel increased 29 % in the first half of this year.

76. A dangerous drug such as Seroquel, indicated to treat merely less than 3.6% of the American population does not achieve "blockbuster" sales without an aggressive, illegal off-label marketing campaign.

99. AstraZeneca has implemented its illegal marketing campaign through its marketing department, sales managers and field sales force, focusing their efforts and resources on the off-label promotion of Seroquel and promoting Seroquel's superior efficacy, tolerability and safety for approved indications with materially misleading statements.

100. Among other things, AstraZeneca caused its pharmaceutical sales representatives to be trained to make false statements to healthcare providers concerning: the efficacy of this medication (including overstating the tolerability of Seroquel by patients who often voluntarily choose to stop taking antipsychotic drugs because of side-effects) and minimizing Seroquel's treatment emergent side effects such as: risk of onset

diabetes; significant weight gain, sexual dysfunction, metabolic syndrome, pancreatitis, hyperlipidemia, and risk of short-term and long-term neurologic movement disorders. AstraZeneca's intentional misbranding of Seroquel was made to increase the market share of Seroquel by and through the creation of the false impression in physicians' minds that Seroquel was safe and effective for a wide range of patients, and that it carried less risk of side-effects and adverse reactions than other available medications. As a result, medical providers were induced to prescribe Seroquel over other medications, mistakenly believing in the superiority of Seroquel.

101. AstraZeneca has also used contrived, self-funded studies in furtherance of its fraud upon publicly and privately funded health care plans. Specifically, AstraZeneca-funded studies were materially misleading in that AstraZeneca's medical collaborators failed to employ proper scientific methodology, clinical research techniques, data interpretation and accurate reporting of results in conducting these studies to support their promotional campaign, and distorted the data derived from its flawed studies in its publications of that data.

102. By way of example, AstraZeneca caused its scientists to employ methodological deficiencies in conducting their studies that intentionally injected bias into the results, thereby guaranteeing a positive outcome for Seroquel. AstraZeneca's repetitive research and publishing activities offered biased, flawed scientific evidence to mislead the medical community as it promoted Seroquel for FDA-unapproved purposes. The AstraZeneca studies were improperly "uncontrolled," "nonrandomized", "unblinded" studies that do not employ accepted scientific methodology to minimize bias in those who collect the data from test subjects and report their findings.

103. "Randomized" studies are those that divide patients into a treatment group and a control group in a random manner akin to the flip of a coin. Randomization helps ensure that both measurable and immeasurable factors are balanced out across both the standard and/or placebo and the new therapy, assuring a fair comparison. Used correctly, it also guarantees that no conscious or subconscious efforts were used to allocate subjects in a biased way. Further, in an experimental study, it is desirable to keep the information about the treatments hidden from the patients and anyone involved with evaluating the patient. This is known as "blinding" or "masking." Blinding prevents conscious or subconscious biases or expectations from influencing the outcome of the study. Similarly, an "uncontrolled" study is one where the clinician providing the treatment is the same physician judging whether the treatment was effective at all while knowing what treatment was received by each patient evaluated.

104. Randomized, blinded, controlled experiments are often considered the highest level of evidence in the scientific methodological hierarchy. In addition, AstraZeneca intentionally conducted studies that were not designed to test the efficacy of Seroquel, yet deceptively use the results of such studies as evidence of Seroquel's safety and effectiveness for off-label treatments.

105. Plaintiff-Relator Kruszewski discovered in his work as a medical-psychiatric consultant for Pennsylvania's Bureau of Program Integrity charged with the responsibility to conduct medical reviews and appeals for the Pennsylvania Department of Public Welfare, through his private practice and while keeping abreast of current developments in his field, that AstraZeneca distorted the results of clinical studies to manufacture otherwise absent "evidence" of Seroquel's comparative efficacy and safety,

failed to disclose material facts about the morbid and potentially fatal side-effects of Seroquel and hawked its drug Seroquel for dangerous off-label indications.

F. *AstraZeneca Has Caused the Submission of False Claims and Records Since 1997.*

77. Prior to the enactment of the Medicare Part D program, Medicaid purchased an estimated 60-75% of Seroquel prescriptions. Because prescriptions for off-label uses generally are not eligible for reimbursement, under Medicaid and Medicare regulations submission of a claim for reimbursement constitutes a false claim for the purposes of the False Claims Act. While it is the pharmacist who physically submits the false claim, a person who knowingly causes such a claim to be filed is equally liable under the law. Here, AstraZeneca's FCA violations arise from its successful attempts to induce others to unwittingly defraud the government.

78. AstraZeneca knew that off-label prescriptions for Seroquel were ineligible for Medicaid reimbursement and that its activities would, in fact, cause numerous ineligible prescriptions to be submitted to Medicaid and Medicare. Hence, the participation of doctors and pharmacists in the submission of false claims was not only foreseeable; it was an intended consequence of AstraZeneca's scheme of fraud.

79. When pharmaceutical companies illegally encourage off-label uses for their drugs, the number of prescriptions rises, thereby causing Medicaid and other programs to pay out more for prescriptions that are not eligible for payment. AstraZeneca intended for its "off-label" promotional campaign to improperly increase the submissions of off-label Seroquel prescriptions, including such prescriptions reimbursed by the Medicare and Medicaid programs.

80. Any claim submitted for a drug when the drug was prescribed for an off-

label use not only violates Medicare payment rules but also files a fraudulent claim under the False Claims Act. 31 USC §3802. AstraZeneca marketed Seroquel for off-label uses in violation of the FCA and knowingly caused doctors and pharmacists to file false reimbursement requests in violation of the False Claims Act.

81. AstraZeneca's marketing for Seroquel's indicated uses have at all times relevant to the complaint been equally fraudulent and misleading. Among other things, AstraZeneca purposefully concealed material facts about the treatment-emergent side effects of Seroquel. This conduct includes:

- suppressing, failing to disclose and mischaracterizing the known risks of Seroquel;
- omitting material information showing that Seroquel was no more effective than other drugs on the market already available;
- the failure to timely and fully disclose the actual results of clinical tests and studies related to Seroquel; and
- the failure to disclose that adequate and/or standard and generally accepted standards for post-marketing testing had not been done.

82. Plaintiff-Relator Kruszewski has researched and analyzed the available scientific data that purports to substantiate the safety and efficacy of Seroquel. His research and detailed analyses expose AstraZeneca's efficacy claims to lack the support of the scientific research AstraZeneca has made publicly available and that AstraZeneca has intentionally obscured, misrepresented or omitted the serious side-effects associated with Seroquel to cast Seroquel in a favorable light.

83. AstraZeneca's illegal and fraudulent promotional scheme contaminated the pool of available information relied upon by medical professionals in their medical decision-making with regard to prescribing Seroquel, thereby putting patients nationwide at risk. As a consequence of the unlawful promotion scheme, patients who were prescribed Seroquel for on and off-label indications were subject to the influence of

unlawful financial inducements provided by AstraZeneca.

84. Absent AstraZeneca's unapproved, illegal off-label marketing, its false representations concerning those medications and its gifts to physicians, Seroquel would not have been prescribed by physicians for off-label indications. AstraZeneca's off-label marketing programs have been extremely successful, leading to the submission of claims to the Medicare and Medicaid programs for medically unnecessary and imprudent prescriptions which otherwise would not have been paid by Medicare and Medicaid.

85. Claims for prescriptions induced to be written and submitted by providers to the Government for reimbursement as a direct and foreseeable result of AstraZeneca's illegal off-label marketing campaign has caused the Plaintiff United States and the Plaintiff States to suffer substantial economic harm. Indeed, the cost of a Seroquel treatment regimen with Seroquel is substantially higher than the available FDA approved medications that would have been prescribed but for AstraZeneca's duplicitous conduct.

86. According to a federal study conducted in 2005, the cost per month for a typical regimen of treatment with Seroquel is approximately $450.00. The comparable cost of a month's treatment with oral haloperidol (Haldol), a first generation antipsychotic, is approximately $37.00 or less, a fraction of the cost of Seroquel.

87. Defendant AstraZeneca's wanton misconduct has been ongoing since 1997 and up to and including the date of the filing of this complaint.

COUNT I
Violation of Federal False Claims Act
31 U.S.C. § 3729, et seq.

88. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator

Kruszewski in the name of the United States under the *qui tam* provisions of 31 U.S.C. § 3730 for Defendant's violations of 31 U.S.C. § 3729.

89. By virtue of the above-described acts, Defendant AstraZeneca knowingly caused to be presented false or fraudulent claims for Seroquel for payment or approval, and continues to cause to be submitted false or fraudulent claims for Seroquel for payment or approval, directly or indirectly, to officers, employees or agents of the United States.

90. Plaintiff United States, unaware of the falsity of the claims and/or statements caused to be made by Defendant AstraZeneca and in reliance on the accuracy thereof, paid said Defendant for claims that would otherwise not have been allowed.

91. The amounts of the false or fraudulent claims caused by the Defendant to be submitted to the United States for Seroquel were material. By reason of Defendant AstraZeneca's wrongful conduct, the United States has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false claim caused to be submitted by Defendant AstraZeneca.

92. Relator-Plaintiff believed and avers that he is an original source of the facts and information on which this action is based.

COUNT II
Violation of False Claims Act
31 U.S.C. § 3729(a)(2)
Creation Or Use Of False Statements Or Records To Obtain Payment

93. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator

Kruszewski in the name of the United States under the *qui tam* provisions of 31 U.S.C. § 3730 for Defendant's violation of 31 U.S.C. § 3729(a)(2).

94. By virtue of the above-described acts, Defendant AstraZeneca knowingly caused to be made or used false records or statements to get false or fraudulent claims for paid or approved by the United States, and continues to make, use or cause false records and statements to be made or used to get false or fraudulent claims for Seroquel paid or approved by the United States.

95. Plaintiff United States, unaware of the falsity of the records and/or statements caused to be made and used by Defendant AstraZeneca, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Seroquel that were ineligible for reimbursement and would not have been paid or approved if any part of the truth were known.

96. The amounts of the false or fraudulent claims caused by the Defendant to be submitted to the United States for Seroquel were material. By reason of Defendant AstraZeneca's wrongful conduct, the United States has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false statement caused to be made or used by Defendant AstraZeneca.

97. Plaintiff-Relator believes and avers that he is an original source of the facts and information on which this action is based.

COUNT III
False Claims Act, 31 U.S.C. §3729(a)(3)
Conspiracy

98. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein. Defendant AstraZeneca entered into conspiracies with paid consultants and public officials for the purpose of defrauding the Plaintiff United States.

99. By the foregoing acts and omissions, Defendant AstraZeneca took actions in furtherance of its conspiracies, including but not limited to the payment of substantial sums of monies to its co-conspirators in exchange for casting favorable light upon Seroquel and for choosing Seroquel to become a first line treatment, thereby exponentially increasing the number of Seroquel prescriptions submitted to the United States for payment.

100. By the foregoing acts and omissions, Defendant AstraZeneca entered into these unlawful marketing conspiracies to defraud the United States by causing false and fraudulent claims to be paid and approved in violation of the False Claims Act, 31 U.S.C. §3729(a)(3).

101. At all times relevant to the complaint, AstraZeneca acted with the requisite knowledge.

102. As a direct and proximate consequence of Defendant AstraZeneca's conspiratorial conduct, the United States has suffered significant, material financial damages in an amount to be proved at trial. The United States *ex rel.* Plaintiff-Relator is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each ineligible Seroquel claims submitted to the United States for payment.

COUNT IV
Illinois Whistleblower Reward and Protection Act

740 ILCS 175/1 *et seq.*

103. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Illinois under the *qui tam* provisions of 740 ILCS 175/4 for Defendant's violation of 740 ILCS 175/3.

104. Defendant AstraZeneca at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Illinois, including Seroquel.

105. By virtue of the above-described acts, among others, Defendant AstraZeneca knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Illinois, for Seroquel.

106. The amounts of the false or fraudulent claims to the State of Illinois were material.

107. Plaintiff State of Illinois, being unaware of the falsity of the claims caused to be submitted by the Defendant, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed Seroquel.

COUNT V
California False Claims Act
Ca. Government Code §12650 *et seq.*

108. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator

Kruszewski in the name of the State of California under the *qui tam* provisions of the California False Claims Act, California Government Code §12651(a).

109. Defendant AstraZeneca at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals, including Seroquel, in the State of California.

110. By virtue of the above-described acts, among others, Defendant AstraZeneca knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of California, for Seroquel.

111. The amounts of the false or fraudulent claims to the State of California were material.

112. Plaintiff State of California, being unaware of the falsity of the claims caused to be submitted by Defendant AstraZeneca and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed Seroquel.

COUNT VI
Delaware False Claims Act
Del. Stat. Tit. VI. §1201

113. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Delaware under the *qui tam* provisions of the Delaware False Claims and Reporting Act, Delaware Statute Title VI, Section 1201.

114. Defendant AstraZeneca at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Delaware, including Seroquel.

115. By virtue of the above-described acts, among others, Defendant AstraZeneca knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Delaware, for Seroquel.

116. The amounts of the false or fraudulent claims to the State of Delaware were material.

117. Plaintiff State of Delaware, being unaware of the falsity of the claims caused to be submitted by the Defendant, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed Seroquel.

COUNT VII
District of Columbia False Claims Act
D.C. Stat. §2-308.03 *et seq.*

118. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the District of Columbia under the *qui tam* provisions of D.C. Stat. §2-308.03 *et seq.*

119. Defendant AstraZeneca at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the District of Columbia, including Seroquel.

120. By virtue of the above-described acts, among others, Defendant AstraZeneca knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the District of Columbia, for Seroquel.

121. The amounts of the false or fraudulent claims to the District of Columbia were material.

122. Plaintiff District of Columbia, being unaware of the falsity of the claims caused to be submitted by the Defendant, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed Seroquel.

COUNT VIII
Florida False Claims Act
Fl. Stat. §§68.081-68.09

123. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Florida under the *qui tam* provisions of Florida False Claims Act, Fl. Stat. §§68.081-68.09.

124. Defendant AstraZeneca at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Florida, including Seroquel.

125. By virtue of the above-described acts, among others, Defendant AstraZeneca caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or

approval, directly or indirectly, to officers, employees or agents of the State of Florida, for Seroquel.

126. The amounts of the false or fraudulent claims to the State of Florida were material.

127. Plaintiff State of Florida, being unaware of the falsity of the claims caused to be submitted by the defendant, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed Seroquel.

COUNT IX
Hawaii False Claims Act
Haw. Rev. Stat. §661-21 *et seq.*

128. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Hawaii under the *qui tam* provisions of Hawaii False Claims Act, Haw. Rev. Stat. §661-21 *et seq.*

129. Defendant AstraZeneca at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Hawaii, including Seroquel.

130. By virtue of the above-described acts, among others, Defendant AstraZeneca knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Hawaii, for Seroquel.

131. The amounts of the false or fraudulent claims to the State of Hawaii were material.

132. Plaintiff State of Hawaii, being unaware of the falsity of the claims caused to be submitted by Defendant, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed Seroquel.

COUNT X
Louisiana Medical Assistance Programs Integrity Law
Louisiana Rev. Stat. §437 *et seq.*

133. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Louisiana under the *qui tam* provisions of the Louisiana Medical Assistance Programs Integrity Law, Louisiana Rev. Stat. §437 *et seq.*

134. Defendant AstraZeneca at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Louisiana, including Seroquel.

135. By virtue of the above-described acts, among others, Defendant AstraZeneca knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Louisiana, for Seroquel.

136. The amounts of the false or fraudulent claims to the State of Louisiana were material.

137. Plaintiff State of Louisiana, being unaware of the falsity of the claims caused to be submitted by the Defendant, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed Seroquel.

COUNT XI

Massachusetts False Claims Act
Massachusetts Gen. Laws c.12 §5(A)

138. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Massachusetts under the *qui tam* provisions of the Massachusetts False Claims Act, Massachusetts Gen. Laws c.12 §5(A).

139. Defendant AstraZeneca at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the Commonwealth of Massachusetts, including Seroquel.

140. By virtue of the above-described acts, among others, Defendant AstraZeneca knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the Commonwealth of Massachusetts, for Seroquel.

141. The amounts of the false or fraudulent claims to the State of Massachusetts were material.

142. Plaintiff Commonwealth of Massachusetts, being unaware of the falsity of the claims caused to be submitted by the Defendant's conspiracies and in reliance on the accuracy thereof, paid and continues to pay for improperly prescribed Seroquel.

COUNT XII
Montana False Claims Act
2005 Mont. Code, CH. 465, HB 146, et seq.

143. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator

Kruszewski in the name of the State of Montana under the *qui tam* provisions of the Montana False Claims Act, 2005 Mont. Code, CH. 465, HB 146, et seq.

144. Defendant AstraZeneca at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals, including Seroquel, in the State of Montana.

145. By virtue of the above-described acts, among others, Defendant AstraZeneca knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Montana, for Seroquel.

146. The amounts of the false or fraudulent claims Defendant caused to be made to the State of Montana were material.

147. Plaintiff State of Montana, being unaware of the falsity of the claims caused to be submitted by the Defendant and in reliance on the accuracy thereof paid and may continue to pay for improperly prescribed Seroquel.

148. At all times relevant to the complaint, AstraZeneca acted with the requisite knowledge.

149. By virtue of the above-described acts, among others, Defendant AstraZeneca knowingly engaged in conspiracies to defraud the Government of Montana by getting a false claim allowed or paid by the government for Seroquel.

150. As a direct and proximate consequence of Defendant AstraZeneca's conspiratorial conduct, the State of Montana has suffered significant, material financial damages in an amount to be proved at trial.

151. The State of Montana would not have suffered these devastating losses had the truth about Defendant's marketing conspiracies been known.

152.

COUNT XIII
Tennessee Medicaid False Claims Act
Tenn. Stat. §§75-1-181 *et seq.*

153. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Tennessee under the *qui tam* provisions of the Tennessee Medicaid False Claims Act, Tenn. Stat. §§75-1-181 *et seq.*

154. Defendant AstraZeneca at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Tennessee, including Seroquel.

155. By virtue of the above-described acts, among others, Defendant AstraZeneca knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Tennessee, for Seroquel.

156. The amounts of the false or fraudulent claims to the State of Tennessee were material.

157. Plaintiff State of Tennessee, being unaware of the falsity of the claims and/or statements caused to be made by the Defendant, and in reliance on the accuracy thereof paid and may continue to pay for Defendant's improperly prescribed drug Seroquel.

COUNT XIV
Texas Medicaid Fraud Prevention Act
Tx. Human Resources Code, Ch. 36, §36.101 *et seq.*

158. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Texas under the *qui tam* provisions of the Texas Medicaid Fraud Prevention Act, Tx. Human Resources Code, Ch. 36, §36.101 *et seq.*

159. Defendant AstraZeneca at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Texas, including Seroquel.

160. By virtue of the above-described acts, among others, Defendant AstraZeneca knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Texas, for Seroquel.

161. The amounts of the false or fraudulent claims to the State of Texas were material.

162. Plaintiff State of Texas, being unaware of the falsity of the claims caused to be submitted by the defendant, and in reliance on the accuracy thereof paid and continues to pay for Defendant's improperly prescribed drug, Seroquel.

COUNT XV
Virginia Fraud Against Taxpayers Act
Va. Stat. Ch. 842, Article 19.1, § 8.01-216.1 *et seq.*

163. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator

Kruszewski in the name of the Commonwealth of Virginia under the *qui tam* provisions of the Virginia Fraud Against Taxpayers Act, Va. Stat. Ch. 842, Article 19.1, § 8.01-216.1 *et seq.*

164. Defendant AstraZeneca at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the Commonwealth of Virginia, including Seroquel.

165. By virtue of the above-described acts, among others, Defendant AstraZeneca knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the Commonwealth of Virginia, for Seroquel.

166. The amounts of the false or fraudulent claims to the Commonwealth of Virginia were material.

167. Plaintiff Commonwealth of Virginia, being unaware of the falsity of the claims caused to be submitted by the Defendant, and in reliance on the accuracy thereof paid and continues to pay for Defendant's improperly prescribed drug Seroquel.

COUNT XVI
Indiana False Claims and Whistleblower Act
(IC 5-11-5.5 *et seq.*)

168. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

169. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Indiana under the *qui tam* provisions of IC 5-11-5.5-4, for the Defendant AstraZeneca's violations of IC 5-11-5.5-2.

170. Defendant AstraZeneca, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Indiana, including Seroquel.

171. Through the acts described above and otherwise, Defendant AstraZeneca knowingly caused to be presented for payment and approval to the Indiana Medicaid program, possibly continues to cause to be presented, directly or indirectly, to officers, employees or agents of the State of Indiana, false and fraudulent claims in order to induce Medicaid reimbursement for Seroquel, and Defendant AstraZeneca's other drugs, that were not eligible for any such reimbursement.

172. Through the acts described above and otherwise, Defendant AstraZeneca knowingly caused to be made or used and continues to cause to be made or used, false and fraudulent statements and/or records, in order to induce Medicaid reimbursement for Seroquel that were not eligible for any such reimbursement.

173. As a result, Plaintiff Indiana reimbursed Medicare and Medicaid participating providers for ineligible claims of Seroquel, resulting in material financial losses to the State of Indiana.

174. Plaintiff State of Indiana, unaware of the falsity of the claims caused to be presented by Defendant AstraZeneca, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Seroquel that would not have been paid or approved in any part if the truth were known.

175. Plaintiff State of Indiana, unaware of the falsity of the records or statements caused to be made or used by Defendant AstraZeneca, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Seroquel that would not have been paid or approved in any part if the truth were known.

176. By reason of Defendant AstraZeneca's wrongful conduct, Indiana has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the state's false claims act in an amount to be determined at trial, plus civil penalties for each such false statement caused to be made or used by Defendant AstraZeneca.

COUNT XVII
Nevada False Claims Act
Nevada Rev. Stat. §357.010 *et seq.*
"Submission of False Claims to State or Local Government."

177. Plaintiffs reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Stefan Kruszewski in the name of the State of Nevada under the *qui tam* provisions of Nevada Rev. Stat. §357.010 *et seq.*, "Submission of False Claims to State or Local Government."

178. Defendant AstraZeneca, at all times relevant to this action, sold and continue to sell pharmaceuticals in the State of Nevada, including Seroquel.

179. At all times relevant and material to this Complaint, Defendant AstraZeneca knowingly caused false claims for payment or approval for Seroquel to be presented to officers and employees of the federal and state governments. As a result, the federal and state governments reimbursed Medicare and Medicaid provider pharmacies for ineligible claims for Seroquel, resulting in great financial loss to the Nevada government.

180. By virtue of the above-described acts, among others, Defendant AstraZeneca knowingly caused to be made or used and continues to cause to be made or used false or fraudulent statements to get claims allowed or paid for Seroquel by the State

of Nevada, for Seroquel.

181. The amounts of the false or fraudulent claims and statements caused to be made by AstraZeneca to the State of Nevada were material.

182. Plaintiff State of Nevada, being unaware of the falsity of the claims and/or statements caused to be made or used by Defendant, and in reliance on the accuracy thereof paid and continues to pay for Defendant's improperly prescribed drug Seroquel.

COUNT XVIII
New Hampshire False Claims Act
(167:61-b *et. seq.*)

183. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of New Hampshire under the *qui tam* provisions of New Hampshire False Claims Act, 167:61-b *et. seq.*

184. Defendant AstraZeneca at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of New Hampshire.

185. Through the acts described above and otherwise, Defendant AstraZeneca knowingly caused to be presented for payment and approval to the New Hampshire Medicaid and Medicare programs, and continues to cause to be presented, false and fraudulent claims, directly or indirectly, to officers, employees or agents of the State of New Hampshire, to induce Medicaid and/or Medicare reimbursement for claims for Seroquel that were not and are not eligible for any such reimbursement.

186. Through the acts described above and otherwise, Defendant AstraZeneca knowingly caused to be made or used, and continues to cause to be made or used, false

and fraudulent records and/or statements, in order to get claims for Seroquel allowed or paid by Medicaid and/or Medicare, that were not eligible for any such reimbursement.

187. The amounts of the false or fraudulent claims to the State of New Hampshire were material.

188. Plaintiff State of New Hampshire, unaware of the falsity of the claims presented or caused to be presented by Defendant AstraZeneca, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Defendant AstraZeneca's drugs that would not have been paid or approved in any part if the truth were known.

189. Plaintiff State of New Hampshire, unaware of the falsity of the records or statements made, used or caused by Defendant AstraZeneca, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Defendant AstraZeneca's Seroquel that would not have been paid or approved in any part if the truth were known.

190. By reason of Defendant AstraZeneca's wrongful conduct, New Hampshire has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus the maximum penalties for each such false statement caused to be made or used by Defendant AstraZeneca and each such false claim caused to be submitted by Defendant AstraZeneca.

COUNT XIX
New Mexico
Medicaid False Claims Act
(740 ILCS 175/3)

191. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of New Mexico under the *qui tam* provisions of the New Mexico Medicaid False Claims Act 740 ILCS 175/3 *et seq.*

192. Defendant AstraZeneca at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of New Mexico, including Seroquel.

193. Through the acts described above and otherwise, Defendant AstraZeneca knowingly caused to be presented for payment and approval to the New Mexico Medicaid and/or Medicare programs, and continues to cause to be presented, false and fraudulent claims directly or indirectly, to officers, employees or agents of the State of New Mexico, in order to induce Medicaid and/or Medicare reimbursement for claims for Seroquel that were not eligible for any such reimbursement.

194. Through the acts described above and otherwise, Defendant AstraZeneca knowingly caused to be made or used, and continues to cause to be made or used, false and fraudulent records and/or statements, in order to get claims for Seroquel allowed or paid by Medicaid and Medicare that were not eligible for any such reimbursement.

195. The amounts of the false or fraudulent claims caused to be made to the State of New Mexico were material.

196. Plaintiff State of New Mexico, unaware of the falsity of the claims presented or caused to be presented by Defendant AstraZeneca, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Seroquel that would not have been paid or approved in any part if the truth were known.

197. Plaintiff State of New Mexico, unaware of the falsity of the records or statements caused to be made or used by Defendant AstraZeneca, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Defendant AstraZeneca's Seroquel that would not have been paid or approved in any part if the truth were known.

198. By reason of Defendant AstraZeneca's wrongful conduct, New Mexico has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus the maximum civil penalty allowed under the state law for each such false claim caused to be submitted by Defendant AstraZeneca and each such false statement caused to be made or used by Defendant AstraZeneca.

COUNT XX
Michigan Medicaid False Claims Act
(M.C.L.A. 400.601 *et seq.*)

199. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Michigan under the *qui tam* provisions of the Michigan False Claims Act, M.C.L.A. 4000.601 *et seq.*

200. Defendant AstraZeneca at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Michigan, including Seroquel.

201. Through the acts described above and otherwise, Defendant AstraZeneca knowingly caused to be presented for payment and approval to the Michigan Medicaid and/or Medicare programs, and continues to cause to be presented, false and fraudulent

claims, directly or indirectly, to officers, employees or agents of the State of Michigan, in order to induce Medicaid and or Medicare to reimburse Medicaid or Medicare participating pharmaceutical providers for Seroquel when those claims were not and are not eligible for any such reimbursement.

202. Through the acts described above and otherwise, Defendant AstraZeneca knowingly caused to be made or used, and continues to cause to be used or made, false and fraudulent records and/or statements, in order to get claims for Seroquel allowed or paid by Medicaid and/or Medicare that were not eligible for any such reimbursement.

203. The amounts of the false or fraudulent claims to the State of Michigan were material.

204. Plaintiff State of Michigan, unaware of the falsity of the claims caused to be presented by Defendant AstraZeneca, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Seroquel that would not have been paid or approved in any part if the truth were known.

205. Plaintiff State of Michigan, unaware of the falsity of the records or statements caused to be made or used by Defendant AstraZeneca, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Seroquel that would not have been paid or approved in any part if the truth were known.

206. By reason of Defendant AstraZeneca's wrongful conduct, Michigan has suffered substantial financial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus the maximum allowable civil penalties for each such false statement caused to made or

used by Defendant AstraZeneca and each such false claim caused to be made by Defendant AstraZeneca.

JURY DEMAND

207. Plaintiffs demand trial by jury on all claims.

PRAYER

WHEREFORE, Relator-Plaintiff, on behalf of himself, the United States government and the Plaintiff States, requests the following relief:

(a) Judgment against Defendant AstraZeneca in the amount of three (3) times the amount of damages the United States of America has sustained because of Defendant AstraZeneca's actions, plus a civil penalty of $11,000.00 for each action in violation of 31 U.S.C. § 3729, and the appropriate fines and penalties for violating the protective federal laws applicable to the fraudulent and false conduct and the cost of this action with interest;

(b) That this Court enter judgment against Defendant AstraZeneca for the maximum amount of damages sustained by each State or District because of the false or fraudulent statements or records caused to be made by Defendant AstraZeneca, plus the maximum civil penalty for each violation of the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175, the California False Claims Act, Cal. Gov. Code §12651(a), the Delaware False Claims and Reporting Act, Del. Stat. Tit. VI. §1201, the District of Columbia False Claims Act, D.C. Stat. §2-308.03 *et seq.*, the Florida False Claims Act, Fl. Stat. §§68.081-68.09, the Hawaii False Claims Act, Haw. Rev. Stat. §661-21 et seq., the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §439, Massachusetts False Claims Act, Mass. Gen. Laws c.12 §5(A), the Michigan

Medicaid False Claims Act, M.C.L.A. 400.601 et seq., the Montana False Claims Act, 2005 Mont. Code, CH. 465, HB 146, et seq., the Nevada False Claims Act, Nevada Rev. Stat. §357.010 et seq., the New Hampshire False Claims Act, 167:61-b et seq., the New Mexico False Claims Act, 740 ILCS 175/3, the Tennessee Medicaid False Claims Act, Tenn. Stat. §§75-1-181 et seq., the Texas Medicaid Fraud Prevention Act, Tx. Human Resources Code, Ch. 36, §36.101 et seq., Indiana False Claims and Whistleblower Act, IC 5-11-5.5 et seq. and the Virginia Fraud Against Taxpayers Act, Va. Stat. Ch. 842, Article 19.1, §8.01-216.1 et seq., plus interest.

(c) That Plaintiffs be awarded the maximum amount allowed pursuant to Illinois Whistleblower Reward and Protection Act, 740 ILCS 175, the California False Claims Act, Cal. Gov. Code §12651(a), the Delaware False Claims and Reporting Act, Del. Stat. Tit. VI. §1201, the District of Columbia False Claims Act, D.C. Stat. §2-308.03 *et seq.*, the Florida False Claims Act, Fl. Stat. §§68.081-68.09, the Hawaii False Claims Act, Haw. Rev. Stat. §661-21 et seq., the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §439, Massachusetts False Claims Act, Mass. Gen. Laws c.12 §5(A), the Michigan Medicaid False Claims Act, M.C.L.A. 400.601 et seq., the Montana False Claims Act, 2005 Mont. Code, CH. 465, HB 146, et seq., the Nevada False Claims Act, Nevada Rev. Stat. §357.010 et seq., the New Hampshire False Claims Act, 167:61-b et seq., the New Mexico False Claims Act, 740 ILCS 175/3et seq., the Tennessee Medicaid False Claims Act, Tenn. Stat. §§75-1-181 et seq., the Texas Medicaid Fraud Prevention Act, Tx. Human Resources Code, Ch. 36, §36.101 et seq., Indiana False Claims and Whistleblower Act, IC 5-11-5.5 et seq. and the Virginia Fraud

Against Taxpayers Act, Va. Stat. Ch. 842, Article 19.1, §8.01-216.1 et seq., plus interest, and all relief to which they are entitled pursuant to said laws

(d) That the Relator-Plaintiff be awarded all costs incurred, including reasonable attorneys' fees;

(e) In the event that the United States or Plaintiff States proceed with this action, Plaintiff-Relator Kruszewski, be awarded an appropriate amount for disclosing evidence or information that the United States and/or the Plaintiff States did not possess when this action was brought to the government. The appropriate amount is not greater than twenty-five percent (25%) of the proceeds of the action or settlement of a claim. The amount awarded to Relator-Plaintiff also includes the results of government actions or settlement of claims resulting from the expansion of claims through the government's further investigation directly generated from or attributable to Relator-Plaintiff's information; and

(f) Such other relief as this Court deems just and appropriate.

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